WE CLAIM:

1. A pharmaceutical composition comprising:

ganciclovir having more than about 1% water content; and

one or more pharmaceutically acceptable excipients,

wherein the ganciclovir retains at least about 97% of its initial purity after one month, at least about 96% of its initial purity after two months, and at least about 95% of its initial purity after three months when stored at 40°C and 75% RH.

2. The pharmaceutical composition according to claim 1, wherein the water content is more than about 1.5%.

3. The pharmaceutical composition according to claim 1, wherein the water content is between about 1% and about 10%.

4. The pharmaceutical composition according to claim 1, wherein the water content is between about 2% and about 6%.

5. The pharmaceutical composition according to claim 1, wherein the one or more pharmaceutically acceptable excipients comprise one or more of diluents, binding agents, disintegrants, wetting agents, lubricants, glidants, and anti-adherent agents.

6. The pharmaceutical composition according to claim 5, wherein the diluent comprises one or more of lactose, starch, mannitol, sorbitol, dextrose monohydrate, microcrystalline cellulose, dibasic calcium phosphate dihydrate, sucrose-based diluents, monobasic calcium sulphate monohydrate, calcium sulphate dihydrate, calcium lactate trihydrate, and powdered cellulose.

7. The pharmaceutical composition according to claim 5, wherein the binding agent comprises one or more of acacia, tragacanth, sucrose, gelatin, glucose, starch, alginic acid, polyethylene glycol, guar gum, polysaccharides, bentonites, polyvinylpyrrolidone, cellulose ethers, hydroxypropyl methylcellulose, and hydroxypropyl cellulose.

8. The pharmaceutical composition according to claim 7, wherein the binding agent comprises between approximately 0.05% and approximately 5% w/w of the composition.

9. The pharmaceutical composition according to claim 6, wherein the disintegrant comprises one or more of starches, sodium starch glycolate, clays, celluloses, purified cellulose, methylcellulose, sodium carboxymethylcellulose, alginates, pre-gelatinized corn starches, crospovidone, and gums.

10. The pharmaceutical composition according to claim 9, wherein the disintegrant comprises between approximately 0.5% and approximately 7% w/w of the composition.

11. The pharmaceutical composition according to claim 10, wherein a portion of the disintegrant is present extragranularly.

12. The pharmaceutical composition according to claim 11, wherein the extragranular disintegrant comprises between approximately 0.5% and approximately 3% w/w of the composition.

13. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition comprises between approximately 80% and approximately 90% w/w ganciclovir, between approximately 6% and approximately 8% w/w microcrystalline cellulose, between approximately 2% and approximately 4% w/w povidone, between approximately 2.5% and approximately 5% w/w croscarmellose sodium, and between approximately 0.25% and 0.75% w/w magnesium stearate.

14. The pharmaceutical composition according to claim 13, wherein approximately half of the croscarmellose sodium is present extragranularly and the other half is present intragranularly.

15. A process for the preparation of a pharmaceutical composition comprising ganciclovir having a water content of more than about 1% and one or more pharmaceutically acceptable excipients, the process comprising:

a) blending the ganciclovir having a water content of more than 1% with the one or more pharmaceutically acceptable excipients;

b) optionally granulating the blend by wet granulation or dry granulation;

c) lubricating the blend of step a) or the granules of step b); and

d) compressing into or filling into a solid dosage form,

wherein the ganciclovir retains at least about 97% of its initial purity after one month, at least about 96% of its initial purity after two months, and at least about 95% of its initial purity after three months when stored at 40°C and 75% RH..

16. The process according to claim 15, wherein the water content is more than about 1.5%.

17. The process according to claim 15, wherein the water content is between about 1% and about 10%.

18. The process according to claim 15, wherein the water content is between about 2% and about 6%.

19. The process according to claim 15, wherein the one or more pharmaceutically acceptable excipients comprise one or more of diluents, binding agents, disintegrants, wetting agents, lubricants, glidants, and anti-adherent agents.

20. The process according to claim 19, wherein the diluent comprises one or more of lactose, starch, mannitol, sorbitol, dextrose monohydrate, microcrystalline cellulose, dibasic calcium phosphate dihydrate, sucrose-based diluents, monobasic calcium sulphate monohydrate, calcium sulphate dihydrate, calcium lactate trihydrate, and powdered cellulose.

21. The process according to claim 19, wherein the binding agent comprises one or more of acacia, tragacanth, sucrose, gelatin, glucose, starch, alginic acid, polyethylene glycol, guar gum, polysaccharides, bentonites, polyvinylpyrrolidone, cellulose ethers, hydroxypropyl methylcellulose, and hydroxypropyl cellulose.

22. The process according to claim 21, wherein the binding agent comprises between about 0.05% and about 5% w/w of the composition.

23. The process according to claim 19, wherein the disintegrant comprises one or more of starches, sodium starch glycolate, clays, celluloses, purified cellulose, methylcellulose, sodium carboxymethylcellulose, alginates, pre-gelatinized corn starches, crospovidone, and gums.

24. The process according to claim 23, wherein the disintegrant comprises between about 0.5% and about 7% w/w of the composition.

25. The process according to claim 24, wherein a portion of the disintegrant is extragranular.

26. The process according to claim 25, wherein the extragranular disintegrant comprises between about 0.5% and about 3% w/w of the formulation.

27. The process according to claim 15, wherein the granules are filled into a capsule.

28. The process according to claim 15, wherein the granules are compressed into a tablet.

29. The process according to claim 15, wherein the granules after the granulation process have a bulk density of at least 0.6 g/ml.

30. The process according to claim 15, wherein the granules after the granulation process have a tapped density of less than 0.8 g/ml.

31. The process according to claim 15, wherein the wet granulation comprises:

granulating the ganciclovir and one or more pharmaceutically acceptable excipients with a binder solution;

drying the granules;

mixing the dried granules with one or more extragranular excipients; and

compressing the resultant blend into a tablet or filling into a capsule.

32. The process according to claim 15, wherein the dry granulation comprises:

dry compaction of the ganciclovir with the one or more pharmaceutically acceptable excipients;

breaking the compacts to generate granules;

mixing the granules with one or more extragranular excipients; and

compressing the resultant blend into a tablet or filling into a capsule.

33. A method of treating infection caused by one or both of cytomegalovirus and herpes simplex virus by administering a pharmaceutical composition to a patient in need thereof, the pharmaceutical composition comprising ganciclovir having more than about 1% water content and one or more pharmaceutically acceptable excipients,

wherein the ganciclovir retains at least about 97% of its initial purity after one month, at least about 96% of its initial purity after two months, and at least about 95% of its initial purity after three months when stored at 40°C and 75% RH.

34. The method of treating of claim 33, wherein the water content of ganciclovir is more than about 1.5%.

35. The method of treating of claim 33, wherein the water content of ganciclovir is between about 1% and about 10%.

36. The method of treating of claim 33, wherein the water content of ganciclovir is between about 2% and about 6%.

37. A ganciclovir capsule for oral administration, the ganciclovir capsule comprising:

ganciclovir having between about 2% and about 6% water content;

between approximately 80% and approximately 90% w/w ganciclovir;

between approximately 6% and approximately 8% w/w microcrystalline cellulose;

between approximately 2% and approximately 4% w/w povidone;

between approximately 2.5% and approximately 5% w/w croscarmellose sodium; and

between approximately 0.25% and 0.75% w/w magnesium stearate,

wherein the ganciclovir retains at least about 97% of its initial purity after one month, at least about 96% of its initial purity after two months, and at least about 95% of its initial purity after three months when stored at 40°C and 75% RH.

38. The ganciclovir capsule according to claim 37, wherein approximately half of the croscarmellose sodium is present extragranularly and the other half is present intragranularly.